IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

THE STATE OF NEW MEXICO ex rel. HECTOR BALDERAS, ATTORNEY GENERAL, Plaintiff, v. STERIGENICS U.S., LLC, SOTERA HEALTH HOLDINGS, LLC, SOTERA HEALTH LLC, and SOTERA HEALTH COMPANY, Defendants.	)	Civil Action No. 1:20-cv-01355

NOTICE OF REMOVAL

Defendant Sterigenics U.S., LLC ("Sterigenics U.S."), by and through its undersigned counsel, hereby files this Notice of Removal pursuant to 28 U.S.C. §§ 1331, 1367, 1441, and 1446, showing the Court as follows:

I. PROCEDURE AND TIMELINESS OF REMOVAL

1. This action is properly removed to this Court pursuant to the federal removal statute, 28 U.S.C. § 1441, because: (i) the action is pending in the Third Judicial District Court in Doña Ana County, which is within the District of New Mexico, and therefore venue is proper under § 1441(a); (ii) the Court has original federal question jurisdiction over the Action under 28 U.S.C. §§ 1331 and 1367; and (iii) the procedural requirements for removal set forth in 28 U.S.C. § 1446 are satisfied.

2. Defendants Sotera Health Holdings, LLC, Sotera Health LLC, and Sotera Health Company have consented to the removal of this action. **Exhibit A.**

3. On December 22, 2020, Plaintiff the State of New Mexico *ex rel.* Hector Balderas, Attorney General of the State of New Mexico, filed a Complaint against Sterigenics U.S., Sotera Health Holdings, LLC, Sotera Health LLC, and Sotera Health Company in the Third Judicial District Court in Doña Ana County, New Mexico, Case No. D-307-CV-2020-02629. With the Complaint, Plaintiff also filed Plaintiff's counsel's verification of the Complaint, and an unsigned Emergency Motion in Support of Request for Ex Parte Temporary Restraining Order and Preliminary Injunction (the "Motion"). Also appearing on the docket is an Order Requiring Scheduling Reports, a Discovery Plan, Expert Witness Disclosure, and Limiting Stipulations to Enlarge Time for Responsive Pleadings. Although no Defendant has yet been served with process, Sterigenics U.S. received a copy of the Complaint, verification and the unsigned Motion from Plaintiff's counsel on December 23, 2020, and waived service of process on December 28, 2020. All documents received by Sterigenics U.S. and on the docket in this case have been attached to the instant Notice of Removal as **Exhibits B–G.** *See* 28 U.S.C. § 1446(a).

4. This Notice of Removal is timely under 28 U.S.C. § 1446(b) because it is filed fewer than 30 days after Sterigenics U.S.'s receipt of the Complaint from Plaintiff's counsel.

5. Sterigenics U.S. will file written notice of the filing of this Notice of Removal with the Clerk of Third Judicial District Court in Doña Ana County, New Mexico concurrently with filing this Notice of Removal and will serve same on Plaintiff pursuant to 28 U.S.C. § 1446(d).

II. GROUNDS FOR REMOVAL

A. Sterigenics U.S.'s Sterilization Facility in Santa Teresa, New Mexico.

6. Sterigenics U.S. is a leading provider of medical product sterilizations in the United States. Since 1989, Sterigenics U.S. has operated a medical products sterilization facility in Santa Teresa, Doña Ana County, New Mexico, (the "Facility") that is registered with and regulated by

the U.S. Food and Drug Administration (the "FDA"). The Facility performs essential ethylene oxide sterilizations of medical products according to processes validated by the FDA in order for them to be used by healthcare providers in critical patient medical procedures. The Facility sterilizes approximately 2.5 million medical products each day. Such products include custom surgical kits, surgical drapes and gowns, cardiovascular tubing sets, internal powered surgical staplers, ophthalmic devices, Band-Aids, prefilled syringes, catheters, tubing for ear, nose, and throat, surgical diagnostic equipment, and tracheostomy-coiled-endotracheal tubes.

7. The need for medical product sterilizations using ethylene oxide is a matter of significant federal importance. The FDA recognizes that "medical devices that are sterilized to remove potentially harmful germs and other microorganisms prior to use are critical to our health care system and a shortage—especially of life-saving, life-sustaining, or other critical devices—can be a detriment to public health." *Statement on concerns with medical device availability due to certain sterilization facility closures*, FDA Statement (Oct. 25, 2019), *available at* https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures. The FDA further recognizes that "ethylene oxide is the most common method of sterilization of medical devices in the U.S. and is a well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and causing infections. More than 20 billion devices sold in the U.S. every year are sterilized with ethylene oxide, accounting for approximately 50 percent of devices that require sterilization." *Id.*

8. According to the FDA, "without adequate availability of ethylene oxide sterilization, we anticipate a national shortage of these devices and other critical devices including feeding tube devices used in neonatal intensive care units, drug-eluting cardiac stents, catheters,

shunts and other implantable devices. It's important to note at this time there are no readily available processes or facilities that can serve as viable alternatives to those that use ethylene oxide to sterilize these devices. In short: this method is critical to our health care system and to the continued availability of safe, effective and high-quality medical devices." *Id.*

9. The FDA recognizes that "the number of ethylene oxide sterilization facilities in the U.S. is limited" and has stated it is "very concerned that additional facility closures could severely impact the supply of sterile medical devices to health care delivery organizations that depend on those devices to take care of patients. The impact resulting from closure of these and perhaps more facilities will be difficult to reverse, and ultimately could result in years of spot or nationwide shortages of critical medical devices, which could compromise patient care." *Id.*

10. Moreover, during the current COVID-19 pandemic, the U.S. Department of Health and Human Services has designated such sterilization services for medical products as "scarce or threatened materials" that are "needed to respond to the spread of COVID-19 and which are, or are likely to be, in short supply . . . ." pursuant to a Notice issued under the President's Executive Order 13970 and section 102 of the Defense Production Act of 1950, 50 U.S.C. § 4512. 85 Fed. Reg. 17592; 85 Fed. Reg. 83975.

B. The Federal Clean Air Act and U.S. Environmental Protection Agency Regulations Govern and Authorize Sterigenics U.S.'s Essential Use and Emissions of Ethylene Oxide Emissions at the Facility.

11. The federal Clean Air Act, an EPA-administrated federal law, regulates the emission of hazardous air pollutants ("HAPs"), including ethylene oxide, in the United States. *See* 42 U.S.C. § 7412.

12. The air emissions from commercial ethylene oxide sterilization facilities in the United States—including Sterigenics U.S.'s Facility—are governed by the Clean Air Act and specific regulations of the U.S. Environmental Protection Agency ("EPA").

13. Under the Clean Air Act, the EPA sets national HAP emissions standards providing for the maximum achievable control technology for emissions of each HAP as determined by the EPA, considering "the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements . . . through application of measures, processes, methods, systems or techniques . . . ." 42 U.S.C. § 7412(d)(2). Those federal emissions standards are set forth in the EPA's National Emissions Standards for Hazardous Air Pollutants, 40 C.F.R. §§ 61 and 63 ("NESHAP").

14. NESHAP sets forth federal standards that "regulate specific categories of stationary sources that emit (or have the potential to emit) one or more hazardous air pollutants listed in section 112(b) of the [Clean Air] Act." 40 C.F.R. § 63.1(a)(2).

15. One of those specific categories is "Ethylene Oxide Emissions Standards for Sterilization Facilities," 40 C.F.R. § 63, Subpart O (the "Federal EO Sterilization Facility Standards").

16. The Federal EO Sterilization Facility Standards provide strict nationwide federal emissions standards governing the operation of medical product sterilization facilities using one or more tons of ethylene oxide annually, which standards must be satisfied in order for such a facility to operate. *Id.* §§ 63.360, 63.362. Those federal regulations include the limits governing the volumes of ethylene oxide that these facilities are allowed to emit for their operations. 40 C.F.R. § 63.362. The regulations also provide the operators' monitoring requirements for ethylene oxide emissions, test methods and procedures, performance measures, work practices, and

reporting requirements. *Id.* §§ 63.364, 63.365, 63.366; *see also id* §§ 63.7, 63.8, 63.10, 63.11 (general NESHAP requirements applicable to ethylene oxide sterilization facilities).

17. The Federal EO Sterilization Facility Standards are based on the EPA's consideration and weight of the "nationwide impacts" the regulations present, including the reduction in "nationwide emissions of EO" from commercial EO sterilization facilities; the potential for the regulations to close sterilization facilities; the economic, financial and operational impacts on commercial EO sterilization operators; and the increased sterilization costs on medical device suppliers and other health-related manufacturers. 59 Fed. Reg. 10591 (Mar. 7, 1994).

C. New Mexico's Federally-Delegated Administration and Enforcement of NESHAP.

18. With certain exceptions, the Clean Air Act and NESHAP provide that the EPA can delegate authority to implement and enforce the Federal EO Sterilization Facility Standards to a state agency according to specific federal criteria and procedures set forth in NESHAP. 42 U.S.C. § 7412(*l*); 40 C.F.R. §§ 63.12(b), 63.368 (a) and (c), 63.90, 63.91. Delegation of such authority must be approved by the EPA and is subject to withdrawal by the EPA if the state fails to adequately implement or enforce the federal standards. *Id.* §§ 63.91, 63.96. Even if such delegation occurs, the EPA retains the authority to implement and enforce the Federal EO Sterilization Facility Standards. 42 U.S.C. § 7413; 40 C.F.R. § 63.368(a).

19. According to 40 C.F.R. § 63.99(32), the EPA has delegated the authority to implement and enforce the Federal EO Sterilization Facility Standards "unchanged" to the New Mexico Department of Environmental Department ("NMED"), which delegation is "subject to all of the conditions and limitations set forth in Federal law and regulations." 40 C.F.R. § 63.99(32). The NMED has no independent state law standards for regulating ethylene oxide emissions from sterilization facilities.

D. Sterigenics U.S.'s NESHAP Permit Issued by the NMED.

20. Sterigenics U.S. operates the Facility under an Air Quality Permit issued by the NMED in accordance with the federal requirements and standards discussed above.

21. That permit states that:

a. The NMED "is the Administrator for 40 CFR Parts 60, 61, and 63 pursuant to the delegation and exceptions of Section 10 of 20.2.77 NMAC (NSPS), 20.2.78 NMAC (NESHAP) and 20.2.82 NMAC (MACT)"[1];

b. The Facility is "authorized for continuous operation";

c. the Facility's allowable emissions are governed by 40 CFR 63, Subparts A and O;

d. The Facility "is subject to 40 CFR, Subparts A and O and shall comply with all applicable requirements of the regulation";

e. Sterigenics U.S. "shall comply with all applicable monitoring requirements of 40 CFR 63, Subparts A and O";

f. Sterigenics U.S. shall comply with all applicable recordkeeping requirements of 40 CFR 63, Subparts A and O"; and

g. Sterigenics is required to comply with the reporting requirements of 40 CFR 63, Subparts A and O.

[1] The referenced delegations are the establishment of state authority to implement new source performance standards, emissions standards for HAPs and emissions standards for HAPs for source categories in accordance with the federal standards. 20.2.77.6 NMAC; 20.2.78.6 NMAC; 20.2.82.6 NMAC. The referenced exceptions concerned the definition of "administrator" for "the purposes of delegation of authority which the administrator of the United States environmental protection agency may, at the administrator's discretion, delegate to the secretary of the New Mexico environment department" and matters unrelated to the Federal EO Sterilization Facility Standards, 20.2.77.10 NMAC; 20.2.78.10 NMAC; 20.2.82.10 NMAC.

E. Plaintiff's Public Nuisance Claims.

22. Plaintiff's chief claims in the first two counts of its Complaint are state law public nuisance claims[2] against Defendants based on Sterigenics U.S.'s use and emission of ethylene oxide from the Facility. Those public nuisance claims include a public nuisance claim under New Mexico's public nuisance statute NMSA 1978 §§ 30-8-1, *et seq.*

23. In support of those claims, Plaintiff's Complaint asserts, *inter alia*:[3]

a. "There is no safe amount of EtO in air or other environmental media." **Exhibit B** ¶63.

b. "Even at very low levels, inhalation of EtO-contaminated air significantly increases the risk of developing cancer and other adverse health effects." *Id.* ¶9.

c. "Defendants received a permit in 1989 and sought, and obtained, various modifications to the original permit over time. These permits and permit modifications contained monitoring and reporting conditions, emission and environmental control parameters, and other terms that Defendants routinely violated." *Id.* ¶125.

d. "EtO emanating from the Santa Teresa Plant—whether from controlled or uncontrolled venting, stacks fitted with scrubbers and other control technologies, or uncontrolled sources such as facility doors and shipping bays, or unaerated equipment in transit—drifted from the Airport Road facility into

[2] Plaintiff's Complaint also asserts claims for Negligence, Strict Liability, and "Violations of New Mexico Unfair Practices Act." **Exhibit B** at pp. 33–37.

[3] Sterigenics U.S. denies Plaintiff's allegations.

the immediately surrounding business park and the residential communities in Santa Teresa only two miles away, and beyond." *Id.* ¶125.

e. "As a result of practices alleged above, Defendants have released potentially dangerous quantities of EtO through controlled and uncontrolled means into the Santa Teresa and Dona Ana County regions, have violated permit conditions requiring all EtO emissions to pass through scrubbers and other environmental control technologies, and breached other material terms on a continuous basis, including emission monitoring and reporting obligations, and otherwise violated New Mexico common and statutory law." *Id.* ¶149.

f. "EtO emitted by Defendants from the Santa Teresa Plant has significantly deteriorated air quality in Santa Teresa and surrounding communities for decades, and has materially contributed to increased health risks suffered by residents of such communities." *Id.* ¶17.

g. "Defendants' emissions of EtO from 1989 until the present have caused significant harm to New Mexico and its residents." *Id.* ¶33.

h. "Defendants' conduct and the presence of EtO annoys, injures, and endangers the comfort, repose, health, and safety of others. *Id.* ¶163, 187.

i. "Defendants' conduct and the presence of EtO interferes with and obstructs the public's free use and comfortable enjoyment of New Mexico natural resources." *Id.* ¶¶164, 188.

j. "Defendants' conduct and the presence of EtO in New Mexico natural resources are injurious to human and environmental health." *Id.* ¶¶165, 189.

k. "An ordinary person would be reasonably annoyed or disturbed by the presence of toxic EtO that endangers human health, and degrades air quality." *Id.* ¶¶166, 190.

l. "Defendants emitted, discharged, or otherwise released toxic contaminants, including EtO, from the Santa Teresa Plant from 1989 to the present, and continue to do so, in a manner that created or participated in the creation of a public nuisance that is harmful to human and environmental health and obstructs the free use of New Mexico natural resources." *Id.* ¶¶161, 185.

24. The relief sought in Plaintiff's Complaint for the alleged public nuisances includes the following:

a. Past and future healthcare costs New Mexico has allegedly suffered, "and other damages to be proven at trial," *id*. ¶200;

b. "Abatement of the allege public nuisance through "an order requiring Defendants to fund a public health monitoring program designed to detect, assess, and treat medical disorders associated with EtO exposure, under State supervision," *id*. ¶201;

c. Declaratory relief; *id.* at p. 39;

d. Punitive damages, *id*. ¶202; and

e. A temporary restraining order and a preliminary injunction enjoining certain allege operational activities at the Facility, *id*. at ¶¶223–31.

25. In addition, NMSA § 30-8-1 provides that the commission of a public nuisance under constitutes a misdemeanor crime. NMSA § 30-8-1.

F. Plaintiff's Public Nuisance Claims Present a Substantial Federal Question under 28 U.S.C. § 1331.

26. Federal-question jurisdiction exists where a plaintiff's cause of action "arises under the Constitution, laws, or treatises of the United States." 28 U.S.C. § 1331. A state-law claim arises under federal law if it implicates significant federal issues. *See Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.,* 545 U.S. 308, 312 (2005). A state-law claim implicates a significant federal issue and satisfies the "arising under" jurisdictional test if a federal issue is: "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013) (citing *Grable,* 545 U.S. at 314).

27. Here, Plaintiff's claims that the Facility's emissions of ethylene oxide constitute a public nuisance raise a substantial federal question conferring subject matter jurisdiction on the Court.

28. An essential element of a public nuisance claim under New Mexico law is the plaintiff's showing that the defendant's act allegedly constituting the public nuisance was taken "without lawful authority." NMSA § 30-8-1; *State ex rel. Smith v. Riley*, 1997-NMCA-063, 12, 123 N.M. 453, 456, 942 P.2d 721, 724 ("Petitioners [who alleged that Respondents made false police reports about them] have not stated a claim under Section 30-8-1 because they have not alleged that Respondents did not have lawful authority make their complaints to the sheriff's department."); *see also Citizens for Alternatives v. Cast Transp.*, No. CIV 99-321 MCA/ACT, 2004 U.S. Dist. LEXIS 34843, at *87 (D.N.M. Sept. 30, 2004) (noting that "without lawful authority" is an "[e]ssential element" of a public nuisance claim under § 30-8-1); *Albuquerque v. State ex rel. Vill. of Los Ranchos de Albuquerque*, 1991-NMCA-015, 15, 111 N.M. 608, 612, 808

P.2d 58, 62 (1991) (no distinction between common law public nuisance and a nuisance under Section 30-8-11 because neither cause of action will exist for an activity authorized by law).

29. Sterigenics U.S. is authorized to use and emit ethylene oxide from the Facility in accordance with the federal Clean Air Act, NESHAP and the Federal EO Sterilization Facility Standards. Plaintiff would have to establish that those governing federal laws are unlawful or do not authorize Sterigenics U.S.'s ethylene oxide emissions at the Facility in order to show that the Facility's emissions were "without lawful authority" and prevail on its public nuisance claims. *See Bader Farms, Inc. v. Monsanto Co.*, No. 1:16-cv-299-SNLJ, 2017 U.S. Dist. LEXIS 21925, *9 (E.D. Mo. Feb. 16, 2017) (where a state law claim necessarily turns on the interpretation and application of a federal regulatory scheme, there is a substantial federal question). Such a federal law question is therefore necessarily raised and actually disputed in Plaintiff's public nuisance claims.

30. Also, this federal question is substantial. It is a pure question of law that is dispositive of the claims: do the federal Clean Air Act, NESHAP and the Federal EO Sterilization Facility Standards authorize the Facility's emission of ethylene oxide as alleged in the Complaint? The question is central to the outcome of Plaintiff's public nuisance claims. *Gilmore v. Weatherford*, 694 F.3d 1160, 1175 (10th Cir. 2012) (courts look "to whether the federal law issue is central to the case in conducting the substantiality analysis"). It also will control other cases in which commercial sterilizers using ethylene oxide for essential FDA-validated medical product sterilizations in accordance with the Clean Air Act and federal EPA authorizations are allegedly acting without lawful authority to create a public nuisance.

31. Moreover, the federal government has a direct and strong interest in both (1) the ability of commercial sterilization facilities to continue essential FDA-validated sterilizations of

critical medical products for adequate national supply in the United States and (2) the authority, operation and enforcement of the federal emissions authorizations and standards it has enacted specifically for such operations to exist and continue. *Grable*, 545 U.S. at 315-16. Clearly, the resolution of this serious federal question "would benefit from 'the advantages thought to be inherent in a federal forum.'" *Nicodemus v. Union Pac. Corp.*, 440 F.3d 1227, 1236 (10th Cir. 2006). Indeed, a case should not be dismissed for want of a substantial federal question unless the federal issue is "(1) wholly insubstantial or obviously frivolous, (2) foreclosed by prior cases which have settled the issue one way or another, or (3) so patently without merit as to require no meaningful consideration." *Id.* at 1235–36.

32. Exercising jurisdiction in this case also will not disturb any congressionally approved balance of federal and state judicial responsibilities.

33. The Court also has supplemental jurisdiction over Plaintiff's other claims for negligence, strict liability and alleged violations of New Mexico's Unfair Practices Act. "In any civil action of which the district courts have original jurisdiction, the district courts shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution." 28 USCS § 1367(a). Here, the Court has supplemental jurisdiction over Plaintiff's remaining claims for negligence, strict liability, and alleged violations of New Mexico's Unfair Practices Act because it has original jurisdiction over the public nuisance claims for the reasons explained above, and those remaining claims are based on the same allegations asserted for Plaintiff's public nuisance claims. *See also Pet Quarters, Inc. v. Depository Trust & Clearing Corp.*, 559 F.3d 772, 779 (8th Cir. 2009) ("If even one claim in the

complaint involves a substantial federal question, the entire matter may be removed.") (citing *Beneficial Nat'l Bank v. Anderson*, 593 U.S. 1, 9 (2003)).

WHEREFORE, by this Notice of Removal, Sterigenics U.S. hereby removes this action from the Third Judicial District Court for the County of Doña Ana, New Mexico and requests that this action proceed as properly removed to this Court.

Respectfully submitted this 28th day of December, 2020.

MODRALL, SPERLING, ROEHL, HARRIS
& SISK, P.A.

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WE HEREBY CERTIFY that on the 28th day of December, 2020, we filed the foregoing electronically through the CM/ECF system and served the following counsel via electronic mail:

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